Agence fédérale des médicaments et des produits de santé
Avenue Galilée 5/03
1210 BRUXELLES

www.afmps.be

DG PRE autorisation/division Recherche et Développement

[redacted]

GlaxoSmithKline Biologicals
[redacted]
Avenue Fleming 20
1300 Wavre

Votre lettre du	Vos références	Nos références	Annexe(s)	Date
25/10/2021		AFMPS/DGPRE/R&D/LFT		18/03/2022

Dossier OGM : B/BE/21/BVW6 (2021-003567-10): A phase 2, single-blinded, randomised, controlled multi-country study to evaluate the safety, reactogenicity, efficacy and immune response following sequential treatment with an anti-sense oligonucleotide (ASO) against chronic Hepatitis B (CHB) followed by chronic Hepatitis B targeted immunotherapy (CHB-TI) in CHB patients receiving nucleos(t)ide analogue (NA) therapy.

[redacted]

Par la présente, nous vous informons que votre demande d'autorisation a été approuvée.

L'autorisation est conforme à l'arrêté royal du 21 février 2005 réglementant la dissémination volontaire dans l'environnement ainsi que la mise sur le marché d'organismes génétiquement modifiés ou de produits en contenant.

Votre autorisation est accordée sur base de l'avis favorable du Conseil de Biosécurité daté du 23 février 2022, aux conditions reprises dans la conclusion de cet avis, à savoir:

"- *The notifier and the investigators must strictly apply the clinical trial protocol, and all the safety instructions as described in the dossier and the new or updated documents. Furthermore, the notifier is recommended to improve, in the document 'Biosafety instructions for site staff", the description of procedures for study staff regarding the management of accidental spills or breakage of a vial containing the GMO (see text proposal in section 4 of this advice). Furthermore, the indication of 5% phenol as desinfectans should be avoided (see section 5 of this advice).*

- Any protocol amendment has to be previously approved by the Competent Authority.

- The notifier is responsible to verify that each study centre has qualified personnel experienced in handling infectious material and that the investigator has the required authorizations to perform the clinical trial activities inside the hospital (laboratory, pharmacy, hospital room, consultation room...) according to the Regional Decrees transposing Directive 2009/41/EC on Contained use of genetically modified micro-organisms.

- At the latest 15 days after the start of the trial, the notifier should provide, along with the delivery of the control sample, a detailed protocol for the method of conservation and analysis of the control sample.

- The Biosafety Advisory Council should be informed within two weeks when the first patient starts the treatment and the last patient receives the last treatment.

- At the latest six months after the last visit of the last patient included in the trial, the notifier must send to the competent authority at the attention of the Biosafety Council a report with details concerning the biosafety aspects of the project. This report will at least contain:

o The total number of patients included in the trial and the number of patients included in Belgium;
o A summary of all adverse events marked by the investigators as probably or definitely related to the study medication;
o A report on the accidental releases, if any, ChAd155-hIi-HBV and MVA-HBV.

- The notifier must provide a report of the shedding data obtained from TH HBV VV-031 HBS:001 (an ancillary study of the main study TH HBV VV-001) (clinical trial 2017-001452-55: Biosafety dossier B/BE/18/BVW4), which was announced to be made available by mid-year 2022."

Sincères salutations,

Frank Vandenbroucke
Vice-Premier Ministre et
Ministre de la Santé publique et
des Affaires sociales

Zakia Khattabi
Ministre du Climat, de
l'Environnement, du
Développement durable et du
Green Deal